

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN, AND
IRBESARTAN PRODUCTS LIABILITY
LITIGATION**

This Document Relates to All Actions

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

Honorable Karen M. Williams,
Magistrate Judge

Honorable Thomas Vanaskie
(Ret.), Special Discovery
Master

**THE ZHP PARTIES' REPLY BRIEF IN FURTHER SUPPORT
OF THEIR OBJECTION TO SPECIAL MASTER ORDER
NO. 28 DENYING A PROTECTIVE ORDER PRECLUDING THE
DEPOSITION OF BAOHUA CHEN**

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I. INTRODUCTION

Special Discovery Master Judge Vanaskie based his decision to deny the ZHP Parties' motion for a protective order under the Third Circuit's apex doctrine, which would preclude Mr. Chen's deposition, on only 6 pages from 5 documents. *See* Special Master Order 28 (ECF No. [1330](#)) ("SMO 28"). Plaintiffs now devote 17 pages of their opposition brief to 35 documents and 9 deposition transcripts in an effort to show no more than, in sum, that Mr. Chen had *some* knowledge pertaining to the ZHP Parties' valsartan. *See* Plaintiffs' Opposition ("Opp.") (ECF No. [1453](#)) at 3-20. Clearly such a showing is legally inadequate under the apex doctrine, as the question is not whether Mr. Chen had some or any knowledge regarding the ZHP Parties' valsartan, but whether Plaintiffs have identified any unique, material knowledge that can *only* be obtained from Mr. Chen through his apex deposition. This Plaintiffs clearly have not done. If Plaintiffs' incorrect interpretation of the apex standard is permitted to prevail, then being at the top of a company's organizational chart, having an educational background generally pertinent to the company the chief executive heads, appearing on the company's website, visiting the company's U.S. subsidiaries once or twice a year, or being recognized, unsurprisingly, as the person with "ultimate authority" at the organization, would be sufficient; therefore, under Plaintiffs' interpretation, the apex doctrine would not need to exist because every CEO's deposition would be common fare in litigation. But this is not the law.

Because Plaintiffs cannot show what they would need to show, Plaintiffs argue, first, that the apex doctrine does not exist in the Third Circuit, and, second, assuming it does, the doctrine should not apply to Mr. Chen. But Plaintiffs are wrong on both counts.

The apex doctrine is the law in the Third Circuit because numerous courts have prohibited the depositions of senior corporate executives on the very basis cited by the ZHP Parties. Nor can Plaintiffs shift what is their own burden onto the ZHP Parties to demonstrate that Mr. Chen does not possess the unique knowledge that is the touchstone of the doctrine. The apex doctrine creates a strong presumption that the deposition of a company's most senior official is unduly burdensome under Rule 26. It was, and remains, Plaintiffs' burden to overcome that presumption by demonstrating clearly and unequivocally that the information they need was not and is not available from a more convenient, less burdensome, and less expensive alternative, such as the extensive depositions of the ZHP Parties' 30(b)(6) and fact witnesses, and the voluminous documentary record that has been made available to Plaintiffs over the past two years. They failed to do that.

For these reasons, as more fully stated below, the ZHP Parties respectfully request that the Court vacate SMO 28, and grant the ZHP Parties' motion for protective order to preclude the apex deposition of Mr. Chen.

II. STANDARD OF REVIEW

The parties disagree as to the appropriate standard of review. Pursuant to Federal Rule of Civil Procedure 53, a Special Master's findings of fact and conclusions of law are reviewed *de novo*, whereas rulings on procedural matters are subject to an abuse of discretion standard. Fed. R. Civ. P. 53(f)(3)-(5). "To determine whether an abuse of discretion or *de novo* standard is appropriate, a district court must look to the type of conclusion or decision made by a special master[.]" *Valeant Pharms. Int'l, Inc. v. AIG Ins. Co. of Canada*, 2020 WL 7768405, at *4 (D.N.J. Dec. 30, 2020). Where, as here, the Special Master interprets case law to make a determination about whether certain requested discovery is permissible, the decision is subject to *de novo* review. *Id.*¹ However, here the reality is that regardless of which standard of review applies, SMO 28 should be reversed and the ZHP Parties' motion for protective order should be granted because Judge Vanaskie simply misapplied the apex doctrine in permitting Mr. Chen's deposition on the basis that Mr. Chen "may" have unique actual knowledge—as opposed to the required finding that Mr.

¹ Plaintiffs argue that an abuse of discretion standard should apply, citing *Engage Healthcare Commc'ns, LLC v. Intellisphere, LLC*, 2017 WL 6539242 (D.N.J. Dec. 21, 2017). See [Opp.](#) at 20. As Plaintiffs note, Judge Goodman authored both *Engage* and *Valeant* ([Opp.](#) at 20), yet *Valeant* was decided most recently and provides an extended and detailed discussion of the appropriate standard of review, whereas *Engage* mentions the abuse of discretion standard in a footnote without analysis. See *Engage*, 2017 WL 6539242 at *2, n.1.

Chen actually has or ever had any such unique knowledge regarding material issues in this case. See [SMO 28](#) at 8.

III. ARGUMENT

A. Plaintiffs Are Required to Rebut the Presumption Against Mr. Chen's Deposition Under the Apex Doctrine in the Third Circuit

1. The apex doctrine is the law of the Third Circuit

Relying on a Sixth Circuit opinion that has not been adopted or cited by any court in the Third Circuit, Plaintiffs argue that the ZHP Parties “overemphasize[] and mischaracterize[]” the apex doctrine. See [Opp.](#) at 22, 23 (citing *Serrano v. Cintas Corp.*, 699 3d 884, 901 (6th Cir. 2021)). But it is indisputable that numerous courts in the Third Circuit, including this Court, have adopted and applied the apex doctrine. See *Younes v. 7-Eleven, Inc.*, 2015 WL 12844446, at *2 (D.N.J. Aug. 19, 2015); see also *George v. Pennsylvania Tpk. Comm’n*, 2020 WL 2745724, at *3 (M.D. Pa. May 27, 2020); *United States ex rel. Galmines v. Novartis Pharms. Corp.*, 2015 WL 4973626, at *2 (E.D. Pa. Aug. 20, 2015); *Ford Motor Co. v. Edgewood Props., Inc.*, 2011 WL 677331, at *2 (D.N.J. Feb. 15, 2011); *Ciarrocchi v. Unum Grp.*, 2009 WL 10676631, at *3 (D.N.J. Aug. 27, 2009); *Piontek v. I.C. Sys.*, 2008 WL 7674787, at *1 (M.D. Pa. Oct. 22, 2008); *Roman v. Cumberland Ins. Grp.*, 2007 WL 4893479, at *1 (E.D. Pa. Oct. 26, 2007); *Reif v. CNA*, 248 F.R.D. 448, 451 (E.D.

Pa. 2008).² Notwithstanding one non-binding Sixth Circuit opinion’s commentary on the apex doctrine,³ upon which Plaintiffs rely, the law in the Third Circuit is that the apex doctrine remains alive and well.

2. Plaintiffs cannot shift their own burden of proof under the apex doctrine to the ZHP Parties

Plaintiffs argue that in opposing this discovery, the ZHP Parties bear the burden of proof under Federal Rule of Civil Procedure 26. *See Opp.* at 24. But such a result would invert the apex doctrine, which, on the contrary, *presumes* that the deposition of a company’s most senior official is unduly burdensome under Rule 26. *See Galmines*, 2015 WL 4973626, at *2 (“The apex doctrine . . . appl[ies] a rebuttable presumption that a high-level official’s deposition represents a significant burden upon the deponent.”). Accordingly, there is no requirement that the ZHP

² Numerous courts across the country agree with courts within the Third Circuit as to the existence and continued vitality of the apex doctrine. *See, e.g., Harris v. Computer Assocs. Int’l, Inc.*, 204 F.R.D. 44, 46 (E.D.N.Y. 2001) (“When a vice president can contribute nothing more than a lower level employee, good cause is shown to not take the deposition.”); *Evans v. Allstate Ins. Co.*, 216 F.R.D. 515, 518-19 (N.D. Okla. 2003) (same); *Folwell v. Hernandez*, 210 F.R.D. 169, 173 (M.D.N.C. 2002) (same); *Baine v. Gen. Motors Corp.*, 141 F.R.D. 332, 335 (M.D. Ala. 1991) (prohibiting apex deposition because “[i]t has also not been demonstrated that [the apex] has any superior or unique personal knowledge” of material issues of liability).

³ Plaintiffs incorrectly characterize *Serrano* as “the published federal appellate decision most directly addressing the ‘apex doctrine.’” *See Opp.* at 22. It is understood that *Salter v. Upjohn Co.*, 593 F.2d 649 (5th Cir. 1979) constitutes the original—and favored—application of the apex doctrine, even if it did not use the term “apex doctrine.” *See Roman*, 2007 WL 4893479, at *1 n.1 (referring to *Salter* as “the leading case on ‘apex depositions’”).

Parties themselves demonstrate any different or additional burden above and beyond that which, by definition, the apex doctrine presumes.⁴ Thus, the burden was and remains on Plaintiffs to overcome the presumption of undue burden by demonstrating that there is no more convenient, less burdensome, and less expensive alternative to Mr. Chen's deposition. *See id.* at *2.⁵ As discussed below, Plaintiffs entirely failed to meet this burden. To date, they still have not identified *any* unique information Mr. Chen has about any material issue that they could not have obtained or have not already obtained via the mountain of discovery the ZHP Parties have provided (including 17 depositions of persons most knowledgeable regarding the issues presented in this litigation).

⁴ Nevertheless, the ZHP Parties have specified that, in addition to facing the burdens confronted by all apex witnesses, to submit to a deposition in this MDL, Mr. Chen would risk his health to travel outside mainland China during the persisting global pandemic to Macau or another country to be deposed. He would also need the assistance of a translator since Mr. Chen does not speak English, increasing a normal 7-hour deposition to 12.25 hours (exclusive of extensive travel time), causing the deposition to extend over a 3-day period due to the twelve-hour time difference. This burden is exceedingly high given Mr. Chen's role as President and the chief executive of a global organization. *See* ECF No. [1386-1](#) at 9; ECF No. [1307](#) at 4, n.1; ECF No. [1247-2](#) at 2. Further, counsel for ZHP has been advised by ZHP that at this time the Chinese government has not issued a travel permit for Mr. Chen to leave China to be deposed in this action.

⁵ Nor do Plaintiffs cite any legal authority for their proposition that the ZHP Parties were "required" to submit a declaration from Mr. Chen or depose their own witnesses regarding Mr. Chen to try to establish a negative, i.e., that he did not have unique knowledge. *See* [Opp.](#) at 24.

B. Plaintiffs’ “Evidence” is, In All Events, Insufficient to Rebut the Presumption Favoring Application of the Apex Deposition to Mr. Chen

Judge Vanaskie misapplied the apex doctrine in denying the motion for a protective order by concluding that Mr. Chen “*may* have some unique knowledge that [Plaintiffs] have been unable to obtain from numerous witnesses deposed thus far.” See [SMO 28](#) at 8 (emphasis added). As the ZHP Parties detailed in their brief in objection to SMO 28 (the “Objection”), the apex doctrine precludes such depositions absent a specific showing by the party requesting the deposition that the witness *actually has* unique, material knowledge. None of the 5 documents on which Judge Vanaskie relied demonstrates that Mr. Chen has any actual unique knowledge regarding the manufacture, sale, and recall of the ZHP Parties’ valsartan that could not have been obtained by Plaintiffs from a readily available and less burdensome source. See Objection at 11-18 (ECF No. [1386-1](#)).⁶

⁶ Plaintiffs speculate that the record of 5 documents on which Judge Vanaskie relied in SMO 28 is “artificially limited” because many of the parties’ exhibits to the underlying briefing were designated as confidential under the Court’s Protective Order. See [Opp.](#) at 25. This suggestion that Judge Vanaskie was somehow hamstrung in preparing SMO 28, and could only cite to non-confidential documents, is factually incorrect and makes no sense. First, out of the 5 documents upon which Judge Vanaskie explicitly relied, 4 were designated confidential or restricted confidential. Second, Judge Vanaskie is not precluded from viewing or relying on information protected by the Protective Order, and could have incorporated such material into his Order in any number of ways without violating the Protective Order’s confidentiality provisions (e.g., describing the material generally (as he did in his opinion), citing to Bates numbers of supporting documents without revealing their

Plaintiffs cannot and do not seriously dispute either of these points. Instead of arguing that Judge Vanaskie appropriately applied the apex doctrine or that the documents on which Judge Vanaskie relied showed any unique information possessed by Mr. Chen, which they do not, Plaintiffs spend the vast majority of their brief discussing documents that Judge Vanaskie did not even rely on in SMO 28 to argue their view that Mr. Chen is the supposed “linchpin of the ZHP organization” as regards ZHP’s valsartan, and had some involvement in matters pertaining to its recall. See [Opp.](#) at 3-20. But, as noted below, Plaintiffs’ “evidence” demonstrates only that Mr. Chen is the classic “apex” witness (i.e., he heads the ZHP Parties, he appears on their websites, he holds himself out as the head of the company with ultimate authority, etc.). Here, the bottom line is that at the end of the day, Plaintiffs have not identified (nor can they identify) any unique knowledge and information material to this case—as defined by Plaintiffs themselves in their 59 30(b)(6) topics—that could only be obtained from Mr. Chen and not from any other employee among the approximately 7,000 at ZHP, including the 17 deponents. That is how Plaintiffs might have rebutted the apex doctrine, but Plaintiffs made no such showing and, in fact, did not come close to doing so.

content, filing his opinion under seal, and/or filing a redacted version of his opinion, etc.).

1. Mr. Chen's role within the ZHP Organization

Plaintiffs claim that Mr. Chen is the “linchpin” between ZHP and its subsidiaries by pointing to an organization chart (ZHP000767000 and ZHP00076708) listing Mr. Chen as CEO of both ZHP and Syncores, one of ZHP's many subsidiaries. *See* [Opp.](#) at 3. Plaintiffs fail to express how this organizational chart adds value to their arguments or indicates that Mr. Chen has any unique knowledge regarding ZHP's subsidiaries, including Syncores.⁷ Moreover, several of the ZHP Party witnesses have already testified as to the roles played by all of the entities within the ZHP organization. *See* ECF No. [1386-1](#) at 5 n.3; ECF No. [1247-2](#) at 17-19. Specifically, Eric Gu, who is the General Manager of Syncores, and Jun Du, who is both the CEO of ZHP's U.S. affiliates and the Vice Chairman of the ZHP Board of Directors, testified extensively about the relationship among the ZHP entities and Mr. Chen's role therein. *See* ECF No. [1295](#) at 5-6.

⁷ Citing to excerpts from 9 ZHP Party witness depositions, Plaintiffs allege that these witnesses have confirmed a narrative that Mr. Chen was “intimately involved with ZHP's manufactured [sic] and recall of valsartan” and is the “linchpin” of the organization ([Opp.](#) at 9-19). However, the excerpts demonstrate the kind of generic, high-level knowledge about a company product that any CEO would be expected to have. None of these excerpts identifies any unique knowledge obtained or possessed by Mr. Chen that others in the organization with direct responsibility would not have. Plaintiffs have already obtained, or have had ample opportunity to obtain, all the material information they need from the 10 30(b)(6) ZHP Party witnesses who have been deposed on 59 topics, along with 7 other ZHP Party fact witnesses. These 10 witnesses, and 7 others, provided a whopping **164.5 hours** of deposition testimony on all 59 topics, and more.

Likewise, Plaintiffs allege, without any factual support, that Mr. Chen’s professional background and degree in chemical engineering demonstrate that he has direct technical knowledge and training and “he effectively leads all of ZHP’s departments and is responsible for coordinating and synthesizing their disparate activities.” See [Opp.](#) at 4. These are nice assumptions, but, truth be told, nothing in Mr. Chen’s professional or educational background establishes that Mr. Chen has unique technical knowledge, let alone information that could not have been obtained from any of the other ZHP Party witnesses, including 9 department heads and lower level employees at each ZHP entity at issue who personally and directly dealt with the development, production, testing, marketing, discovery of nitrosamines and recall of valsartan.⁸ See ECF No. [1295](#) at 2-4. Moreover, as Jun Du and other ZHP senior executives testified, the substantive decision-making in the key areas in this case was made by the principals in the relevant departments, all of whom have been deposed by Plaintiffs—and not by Mr. Chen. See ECF No. [1295](#) at 3-4, 8-10.

2. Mr. Chen’s interactions with the FDA

Plaintiffs claim that Mr. Chen’s attendance at FDA plant inspections—none of which concerned the valsartan nitrosamine impurities at issue here—as the most

⁸ In fact, the deposition testimony of Jucai Ge demonstrates that Mr. Chen “never was involved” in specific product development or deviation investigations. See ECF No. [1247-2](#) at 9; ECF No. [1295](#) at 8.

senior executive at the company illustrates that he played a central role in the ZHP Parties' interactions with the FDA. *See* [Opp.](#) at 4-5. Other than Mr. Chen's attendance at certain opening and closing meetings during those inspections, Plaintiffs have not produced any evidence to support Mr. Chen's alleged central role in ZHP's interactions with the FDA that are pertinent in this case, despite having had the opportunity to depose no fewer than 11 ZHP Party witnesses on this very topic. *See* ECF No. [1247-2](#) at 20-23; ECF No. [1295](#) at 6-8. Nor can Plaintiffs identify any information regarding ZHP's interactions with the FDA about the valsartan nitrosamine impurities that was not provided, or could not have been provided, by any of the 11 ZHP Party witnesses who testified.⁹ Instead, the evidence shows that any involvement Mr. Chen had with the FDA was customary in his role as the company's chief executive, formality-driven and extremely limited, as the relevant

⁹ Plaintiffs point to the testimony of Jun Du regarding ZHP's August 26, 2018 response to the FDA's 483 notifications arising from the July and August 2018 FDA inspections about the nitrosamine impurities as confirmation that none of the ZHP party witnesses whom Plaintiffs deposed were able to "fill in the gaps that only Baohua Chen can." *See* [Opp.](#) at 9. But the testimony they cite actually illustrates the contrary. For example, when asked whether he reviewed the FDA letter, Jun Du testified that it was "completed by the QA department, QC department, technology department, and analytical department of ZHP"—employees of which Plaintiffs have deposed. *See id.* at 10. Nothing in Jun Du's testimony even remotely suggests that Mr. Chen, who *did not even attend* these 2018 FDA inspections, would have any unique knowledge regarding ZHP's response to the FDA given that it was prepared by the members of ZHP's identified departments on whose professional competence Mr. Du (Mr. Chen's subordinate) relied.

ZHP Party departments handled all substantive aspects of these inspections and company's responses to the FDA observations. *Id.*

3. Mr. Chen's knowledge of ZHP's sales and pricing for valsartan

Plaintiffs also speculate that "Mr. Chen micromanaged the price" for valsartan API and "spearheaded" the strategy to cut costs via a manufacturing process change with Syncores, a ZHP affiliate. *See Opp.* at 5-6. This includes Plaintiffs' allegations, which are wholly without factual support in the case record, that Mr. Chen [REDACTED]

[REDACTED] *See id.* at 6.¹⁰ Again, Plaintiffs have failed to present any evidence to support these unfounded, speculative claims despite having already obtained testimony from at least 8 ZHP Party witnesses regarding these very topics. *See* ECF No. [1247-2](#) at 23-25; [1295](#) at 9-10.

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[REDACTED] Further, Plaintiffs have questioned 8 ZHP Party witnesses about it (including asking Jun Du *more than 100 questions* about it for nearly 3 hours), including 3 witnesses who were recipients of the email (Jucai Ge, Min Li, and Linda Lin) and who have already testified about this document. *See* ECF No. [1295](#) at 12. None, it should be noted, linked Mr. Chen to this email in any way.

The documents on which Plaintiffs rely show that (1) Mr. Chen was CEO of Syncores; (2) Mr. Chen asked questions about the cost of manufacturing valsartan; and (3) Mr. Chen took a general interest in his company's sales and pricing data, as would be expected of any "apex witness". None of this information is unique to Mr. Chen, nor was it unobtainable if not actually already obtained from any of the other ZHP Party deponents.

4. Mr. Chen's involvement in the recall and customer complaints

Plaintiffs claim that Mr. Chen "was also intimately involved with ZHP's recall of valsartan" based on a document described as ZHP's "Protocol of Valsartan API Recall (foreign grade)" that lists Mr. Chen as a member of a "Recall Group." [Opp.](#) at 6-7. Leaving aside the fact that a document listing Mr. Chen as one among several members of a group is unlikely to indicate any unique information on Mr. Chen's part, this claim has been directly refuted by the testimony of 5 ZHP Party witnesses—Yuelin Hu, Qiangming Li, Jucai Ge, Eric Gu, and Hai Wang—of whom Yuelin Hu, Qiangming Li, and Jucai Ge were members of the so-called "Recall Group." *See* [Opp.](#) at 6; ECF No. [1295](#) at 10-11. The record demonstrates that Mr. Chen's role in the recall, if any, was extremely limited, and any attendance by him at meetings was only to receive updates and reports from those ZHP Party witnesses who have testified. *See* ECF No. [1247-2](#) at 26-27. Moreover, Plaintiffs had the opportunity to question ZHP Party 30(b)(6) and fact witnesses extensively about

every aspect of the valsartan recall, including Mr. Chen’s role, limited as it was, in interacting with regulatory authorities and communicating with customers, including Novartis and Teva about the recall, and Plaintiffs have failed to produce any evidence that Mr. Chen possesses *unique* information that would not be duplicative of testimony already given by his subordinates.

Likewise, Plaintiffs’ reliance on a two-and-a-half page unsigned draft letter purportedly to be signed by Mr. Chen and directed to the European Directorate for the Quality of Medicines (EDQM) as supposed evidence of Mr. Chen’s “intimate” involvement with ZHP’s recall of valsartan ([Opp.](#) at 7-8) is inapposite where, in fact,

[REDACTED]

[REDACTED], which was explained in depth at Jun Du’s deposition and the depositions of the ZHP employees and department heads who carried out the root cause investigation and evaluation—Min Li, Peng Dong, Jucai Ge, Qiangming Li, Eric Tsai, and Eric Gu, all of whom were deposed or could have been deposed about this subject. *See* ECF No. [1295](#) at 7-8. Nothing in the unsigned draft letter to the EDQM (which was not drafted by Mr. Chen) shows that Mr. Chen possesses any unique knowledge about the root cause assessment that would not duplicate the information already provided by Jun Du or the ZHP department heads.

Finally, Plaintiffs point to Mr. Chen’s purported “handling” of certain customer complaints following the recall as evidence of his intimate involvement

and oversight of the recall. Opp. at 8-9. Again, Plaintiffs engage in pure speculation in making this argument. The documents to which Plaintiffs point contain only a handful of general statements by Mr. Chen as his company's chief executive officer to customers to assuage their concerns following the recall. They certainly do not suggest, much less in any way actually establish, that Mr. Chen had any unique knowledge about the nitrosamine impurities in valsartan or the recall.

IV. CONCLUSION

For all of the foregoing reasons, and those stated in the ZHP Parties' prior briefing on this issue, incorporated by reference herein, the ZHP Parties respectfully request that the Court vacate and reverse SMO 28 and grant the Motion for Protective Order as to the apex deposition of Mr. Chen.

Dated: August 9, 2021

Respectfully submitted,

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